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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,384	08/19/2003	Kenneth Brasel	A9169	4836

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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
12/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,384	BRASEL ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/31/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 07/24/2008, has been entered.

Claims 1-23 are pending.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

This Office Action will be in response to applicant's arguments, filed 07/24/2008.

The rejections of record can be found in previous Office Actions, mailed 10/06/2006, 05/03/2007 and 01/29/2008.

Again, it is noted that applicant's arguments and the examiner's rebuttal are essentially the same of record and will be addressed in the following Priority Section.

3. Priority.

Applicant's arguments including reliance upon In re Johnson and Farnham, 194 USPQ 187 (CCPA 1977), Hybritech Inc. v Monclonal Antibodies, Inc., and MPEP 2163, filed 07/24/2008, have been fully considered but have not been found convincing with respect to the priority of the instant claims essentially for the reasons of record.

Again, it is noted that applicant's arguments concerning that the filing date of USSN 08/725,540, filed 10/03/1996, is the effective filing date of the instant claims and the examiner's rebuttal are essentially the same of record.

With respect to applicant's arguments that Claims 1-23 are Adequately Supported for the Treatment of all Infections and Claims 1-23 are Adequately Supported for the Proviso to exclude HIV,
the following, including that of record, is noted.

Again, applicant's reliance
upon page 3 of USSN 08/725,540, which discloses that: "the invention also provides a method of augmenting an immune response in a patient that has an infectious disease wherein the method comprises the step of administering an amount of flt3 ligand sufficient to increase the patent's number of dendritic cells" and
upon page 11 of USSN 08/725,540, which discloses "increasing / mobilizing dendritic cells in vivo to antigens such as tumor antigen, bacterial antigen or viral antigen"
is / has been acknowledged.

As addressed previously, applicant submission that that it is clear that the instant specification and the priority applications disclose treatment of infection generally as the presence of the bacterial or viral antigen in the patient would arise as a result of the patient being infected with the bacteria or virus and that two species (e.g., "viral or bacterial antigens/infection") of the genus are described has been acknowledged.

While, it is noted that "infection" is broad, that "viral and bacterial infections" are broad as well albeit "bacterial and viral infections" that can be considered species of the broader genus of "infection";
the current claims now rely upon "HIV" as a species that is yet another class/subgenus/species that is much smaller than either "infection or viral / bacterial infections" originally disclosed in the instant or priority applications.
"Infections", "viral/bacterial infections" and "HIV infection" differ in orders of magnitude.

However, as pointed out previously, the current claims now rely upon "HIV" as a species that is yet another class/subgenus/species that is much smaller than either "infection or viral / bacterial infections" originally disclosed in the instant or priority applications.

In contrast to applicant's assertions concerning "infections",
it is the recitation of the negative limitation of "with the proviso that said infectious disease is not HIV" that is at issue (see Claims 1-23 are Adequately Supported for the Proviso to exclude HIV).

Therefore, it appears that applicant's arguments concerning the issues presented in the Section entitled Claims 1-23 are Adequately Supported for the Treatment of all Infections per se are not the key issue to the written description issues at hand per se.

Applicant relies upon 37 CFR 1.57 and MPEP 2163.07(b) and the disclosure of priority USSN 08/725,540 to support the clear intent to incorporate by reference the entirety of the cited patents into the specification of USSN 08/725,540.

Page 4, lines 33-35 of USSN 08/725,540 discloses the following.

As used herein, the term "flt3-1igand" refers to a genus of polypeptides that are described in United States Patent No. 5,554,512, EP 0627487 A2 and in WO 94/28391, all incorporated herein by reference.

While, an application is entitled to rely upon the filing date of an earlier application, even if the earlier application itself incorporates essential material by reference to another document (see Ex parte Maziere, 27 USPQ2d 1705, 1706-07 (Bd. Pat. App. & Inter. 1993) and MPEP 608.01(p));
applicant is reminded that to incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where the material is found in the various documents.

See Advanced Display Systems, Inc. v. Kent State Univ., 54 USPQ2d 1673 (Fed. Cir. 2000) citing In re Seversky, 177 USPQ 144, 146 (CCPA 1973).

Also see MPEP 608.01(p) as follows.

Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). >37 CFR 1.57(b)(1) limits a proper incorporation by reference (except as provided in 37 CFR 1.57(a)) to instances only where the perfecting words "incorporated by reference" or the root of the words "incorporate" (e.g., incorporating, incorporated) and "reference" (e.g., referencing) appear. The requirement for specific root words will bring greater clarity to the record and provide a bright line test as to where something is being referred to is an incorporation by reference. The Office intends to treat references to documents that do not meet this "bright line" test as noncompliant incorporations by reference and may require correction pursuant to 37 CFR 1.57(g). If a reference to a document does not clearly indicate an intended incorporation by reference, examination will proceed as if no incorporation by reference statement has been made and the Office will not expend resources trying to determine if an incorporation by reference was intended.< In addition to other requirements for an application, the referencing application *>must< include an identification of the referenced patent, application, or publication. >See 37 CFR 1.57(b)(2)< Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. Guidelines for situations where applicant is permitted to fill in a number for Application No. _____ left blank in the application as filed can be found in In re Fouche, 439 F.2d 1237, 169 USPQ 429 (CCPA 1971) (Abandoned applications less than 20 years old can be incorporated by reference to the same extent as copending applications; both types are open to the public upon the referencing application issuing as a patent. See >37 CFR 1.14(a)(i)(iv) and (vi) and< MPEP § 103).

Note, too, that MPEP 2163.07(b) directs one to MPEP 608.01(p) for guidance regarding incorporation by reference.

Further, it is noted that USSN 08/725,540 did not rely upon U.S. Patent No. 5,554,512, filed as USSN 08/243,545 for priority and, more particularly, incorporation by reference as a priority document.

Therefore, the priority application USSN 08/725,540 appears to only rely upon U.S. Patent No. 5,554,512 for a description of "flt3-ligand"
and not for the disclosure of treating patients having infectious diseases in the context of "with the proviso that said infectious disease is not HIV".

In contradistinction to applicant's reliance upon In re Johnson and Farnham,
applicant's reliance upon the instant and priority applications do not provide sufficient disclosure of a broad and complete disclosure coupled with extensive examples fully supported of the limited genus encompassing the negative proviso now claimed.

Therefore, it is maintained that the negative proviso introduces a new subgenus, where the specification nor the priority documents provide a sufficient description of the species HIV itself.

In addition, it is maintained that the negative proviso introduces a new subgenus, where the specification and the priority documents do not provide a sufficient number of species to establish entitlement to the claimed negative proviso reciting "HIV".

With respect to applicant's reliance upon USSN 09/444,072 for support for the "proviso that the infectious disease is not HIV";
again, it is noted that USSN 09/444,072 does not provide written support for "HIV" or "treating patients with an infection with HIV".

Again, the recitation of HIV is not readily apparent in the specification as filed, nor in the priority documents.
In turn, the support for "with the proviso that said infectious disease is not HIV" is not readily apparent in the specification as filed.

Again, while negative limitations as set forth in the newly submitted "proviso" may be satisfactory in certain circumstances,
there must be written support for the negative limitation in the application as filed.

Therefore, the examiner maintains that the filing date of the instant claims is deemed to be the filing date of instant USSN 10/643,384, filed 8/19/2003.
Again, if applicant desires priority prior to 08/19/2003 for the instant claims,
applicant is invited to point out and provide documentary support for the priority of the instant claims.

Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

Therefore, while applicant notes that the instant application is filed as a Divisional of pending USSN 10/241,927, which is a continuation of USSN 09/444,027;
it is maintained that this application repeats a substantial portion of prior USSN 10/241,927, filed 09/11/2002 and adds and claims additional disclosure not presented in the prior application, as indicated above.

Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Therefore, applicant should amend the first line of the specification to indicate the status of the instant application as a continuation-in-part.

A claim as a whole has only one effective filing date.
See Studiengelsellschaft Kahle m.b.H. v. Shell Oil Co. 42 USPQ2d 1674, 1677 (Fed. Cir 1997).

In contrast to applicant's assertions indicating the examiner's reasoning casts serious doubts on the reliable use of the incorporation by reference expedient,
the examiner maintains that the reasoning of record and address herein is consistent with incorporation by reference policy and guidelines, as set forth in the MPEP.

Applicant's arguments have not been found persuasive.

4. This is a rejection under 35 USC, 112, first paragraph, Written Description / New Matter.

Claims 1-23 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.
The specification as originally filed does not provide support for the invention as now claimed: "with the proviso that said infectious disease is not HIV".

Applicant's arguments, filed 07/24/2008, and the examiner's rebuttal concerning the issues of priority and how they may factor into this rejection are set forth above in the Section on Priority.

The following of record is reiterated for applicant's convenience.

Applicant's amendments, filed 02/07/2007, does not appear to provide sufficient direction to this "negative proviso" in the specification as filed.

The recitation of HIV is not readily apparent in the specification as filed.
In turn, the support for "with the proviso that said infectious disease is not HIV" is not readily apparent in the specification as filed.

While negative limitations as set forth in the newly submitted "negative proviso" may be satisfactory in certain circumstances,
there must be written support for the negative limitation in the application as filed.

Applicant's amendment filed 02/02/2007, does not appear to provide sufficient written support for HIV and in turn, does not appear to provide sufficient written support for the proviso as well.

The specification as filed does not provide a written description or set forth the metes and bounds of this phrase. The specification does not provide blaze marks, nor direction for the instant methods encompassing the above-mentioned "negative proviso", as currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.
Applicant is required to cancel the new matter in the response to this Office Action

Alternatively, applicant is invited to provide sufficient written support for the "negative proviso" indicated above.
See MPEP 714.02 and 2163.06

Applicant's arguments have not been found persuasive.

5. Claims 1-23 stand rejected under 35 U.S.C § 102(e) as being anticipated McKenna et al. (US 2004/0022760) (see entire document, particularly Summary of the Invention and Detailed Description of the Invention) essentially for the reasons of record.

Applicant's arguments, filed 07/24/2008, and the examiner's rebuttal concerning the issues of priority and how they may factor into this rejection are set forth above in the Section on Priority.

Applicant's arguments have been fully considered but have not been found convincing essentially for the reasons of record and that addressed above in the Sections on Priority and Written Description/New Matter.

A claim as a whole has only one effective filing date.
See Studiengelsellschaft Kahle m.b.H. v. Shell Oil Co. 42 USPQ2d 1674, 1677 (Fed. Cir 1997).

Applicant's arguments have not been found persuasive.

The following is reiterated for applicant's convenience.

McKenna et al. teach the use of Flt3-ligand (e.g., see paragraphs [0054] – [0068]) in immunization protocols (e.g., see Therapeutic applications in paragraphs [0089] – [0159]), including its use as an adjuvant in vaccines comprising bacterial and viral antigens (e.g., see paragraphs [0078] –[0085], including Table 1 on pages 10-11 and paragraphs [0127] – [0129]) as well as known pharmaceutical compositions (e.g. see paragraphs [0085], [0092], [[0096] - [0120]) and modes of administration (e.g., see paragraphs [0121] –[0126] recited and encompassed by the claimed methods.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

6. Claims 1-23 stand rejected under 35 U.S.C § 102(e) as being anticipated Rosenthal et al. (U.S. Patent No. 6,875,441) (see entire document, particularly Summary of the Invention and Detailed Description of the Invention) essentially for the reasons of record.

Applicant's arguments, filed 07/24/2008, and the examiner's rebuttal concerning the issues of priority and how they may factor into this rejection are set forth above in the Section on Priority.

Applicant's arguments have been fully considered but have not been found convincing essentially for the reasons of record and that addressed above in the Sections on Priority and Written Description/New Matter.

A claim as a whole has only one effective filing date.
See Studiengelsellschaft Kahle m.b.H. v. Shell Oil Co. 42 USPQ2d 1674, 1677 (Fed. Cir 1997).

Applicant's arguments have not been found persuasive.

The following is reiterated for applicant's convenience.

Rosenthal et al. teach the use of Flt3-ligand (e.g., see Background of the Invention, column 7, paragraph 3 and Examples) in immunization protocols (e.g., see column 11, paragraph 6) including its use as an adjuvant in vaccines comprising bacterial and viral antigens (e.g., see column 11, paragraphs 6-7) as well as known pharmaceutical compositions and modes of administration (e.g., see columns 12-13) recited and encompassed by the claimed methods.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

7. Claims 1, 3-9, 11-15 and 17-23 stand rejected under 35 U.S.C § 102(b) as being anticipated Lyman et al. (U.S. Patent No. 5,554,512) (see entire document, particularly Summary of the Invention and Detailed Description of the Invention) essentially for the reasons of record.

Applicant's arguments, filed 07/24/2008, and the examiner's rebuttal concerning the issues of priority and how they may factor into this rejection are set forth above in the Section on Priority.

Applicant's arguments have been fully considered but have not been found convincing essentially for the reasons of record and that addressed above in the Sections on Priority and Written Description/New Matter.

A claim as a whole has only one effective filing date.
See Studiengelsellschaft Kahle m.b.H. v. Shell Oil Co. 42 USPQ2d 1674, 1677 (Fed. Cir. 1997).

Applicant's arguments have not been found persuasive.

The following of record is reiterated for applicant's convenience.

Lyman et al. teach the use of Flt3-ligand (e.g., see columns 4-17 and Examples) [0068]) as well as known pharmaceutical compositions and modes of administration (e.g., see column 18, paragraphs 3-4) that can be use in methods to stimulate T cell proliferation as well hemopoietic cells in treating patients with HIV (e.g. see column 7, paragraph 3) encompassed by the claimed methods.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure.

It is noted that even if applicant is able to obtain the earliest priority document relied upon, this reference would still stand as prior art under 35 USC 102(e).

8. No claim is allowed.

9. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/

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